REMARKS

I. Status of the Claims

Claims 13-22, 37-46, and 49-52 are pending in this application. Claims 1-12, 23-36, 47, and 48 were canceled in the Preliminary Amendment filed on June 15, 2006. Applicant amends claims 13-22, 37-46, 50, and 51 for clarification and to correct grammatical errors. Claims 39 and 51 are further amended to correct antecedence. Support for new claim 52 may be found throughout the specification, for example pages 1, 6-7, and 15. No new matter is added by any of the amendments herein.

II. Rejection Under 35 U.S.C. § 112, Second Paragraph

The Office rejects claims 15 and 41 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. Office Action at page 2. The Office refers to "[a] broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) . . . ." *Id.* Applicants note that the original claims were amended in the Preliminary Amendment filed on June 15, 2006. Thereafter, claims 15 and 41 recite one range: an EPA:DHA ratio from about 1:1 to 1:8. Applicants therefore respectfully request that the Office reconsider and withdraw this rejection.

III. Rejection Under 35 U.S.C. § 112, First Paragraph

The Office rejects claims 13-22, 37-46, and 49-51 under 35 U.S.C. § 112, first paragraph, for lack of enablement. Office Action at page 3. The Office contends that "the specification, while being enabling for controlling body weight reduction, does not reasonably provide enablement for prevention of body weight gain." *Id.* Applicants respectfully traverse the rejection.

35 U.S.C. § 112, first paragraph, requires that the specification describe the invention and "the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same ...." Further, the M.P.E.P. provides that the Office bears the initial burden of presenting evidence demonstrating why one of ordinary skill in the art would not find enabling disclosure in the application specification to support the claims. *See* M.P.E.P. § 2163(II)(A). Applicants submit that the Office has failed to meet this burden.

As an initial matter, the Office alleges that claims 15 and 41 recite both a broad and narrow limitation. Office Action at page 3. As Applicants showed above, claims 15 and 41 recite one range, and therefore do not demonstrate a lack of enablement.

The Office then considers various factors in regards to the "preventative limitation":

(A) The breadth of the claims;
(B) The nature of the invention;
(C) The state of the prior art;
(D) The level of one of ordinary skill;
(E) The level of predictability in the art;
(F) The amount of direction provided by the inventor;
(G) The existence of working examples; and
(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Id. at pages 3-5. *See also In re Wands*, 858 F.2d 731, 8 U.S.P.Q. 2d 1400 (Fed. Cir. 1988). According to the Office, "[t]he quantity of experimentation sufficient enough in order to determine a clear inventive objective drawn to preventative achievement is absent." Office Action at page 4. In particular, the Office asserts the following:

> Accordingly, though animal models are reasonably representations drawn to determine safety and efficacy in humans, the experiments of the claimed invention directed to mice models do not support nor suggest a clear method of prevention in human subjects. The studies disclosed within the instant specification (pages 24-35) are replete with drug-regimen protocols which one of ordinary skill would readily determine to be a representative treatment in the reduction of the said disorder. However, the same seven studies in the instant specification do not adequately address the limitation drawn to prevention.

Id. at page 5. Applicants disagree.

Study 6, entitled "Prevention of body weight gain and obesity," reports that mice fed a high-fat (HF) diet in which a portion of the lipids were replaced by omega-3 fatty acids gained less weight gain relative to a control group fed the HF diet alone. *See* Applicants' specification at pages 30-33. The results shown in Figure 5B further support prevention of body weight gain in accordance with Applicants' claims:

> Weight gain was apparent after about 2 weeks of habituation on the HF diet and reached about 6.5 g within the next 5 weeks of the experiment. Body weight gain was about 2.7 g lower in mice fed a HF composite diet where 15% lipids in the diet were replaced by omega-3 product EPAX 1050 TG (rich in DHA) compared to mice fed only the HF composite diet. This states that even a low dose of omega-3 product (only 15% w/w of the fat content of the diet) slowed down the development of obesity in ad libitum fed mice.

Id. at page 31, ll. 16-25.

The specification also provides the following definition for prevention: "[a]s used herein the term prevention of body weight gain also means inhibiting body weight gain and effecting or controlling weight loss." *See* specification at page 21, ll. 12-15. Thus the Office errs in alleging that "the term *prevention* is disclosed only twice in the entire specification (pg 1) but is absent of any definition, description, and/or explanation of

prevention as it is presented in the instant claim set." Office Action at page 5 (emphasis original).

Furthermore, the Office provides no reason why the skilled artisan would not find Applicants' disclosure, including Study 6 described above, enabling towards prevention recited in the claims.

The Office further contends that "the various dosage forms as disclosed that may comprise a dietary product are not presented with adequate elucidation to properly suggest to one or ordinary skill that there is possession of preventative achievement." Office Action at page 4. Applicants refer the Office to the specification at pages 35-37 under the heading "Doses of the Fatty Acid Composition." That section of the specification teaches, among other things, that "[t]he relative content of the fatty acid composition according to the invention with respect to the total lipid content (in the diet) may be more important than the absolute intake, as far as the effect on weight reduction is concerned." *See* page 35, ll. 23-27. One of ordinary skill in the art would recognize that the same approach to dosage is applied in Study 6, wherein mice received diets where 15% or 44% of the lipids were replaced by omega-3 fatty acids. *Id.* at page 30 and Figures 5A and 5B.

In addition, Applicants' specification teaches that, "[c]oncerning the dose, the results from mice may be extrapolated to humans, as far as the relative content of the fatty acid composition according to the invention, for instance an fatty acid composition containing EPA and DHA or any combinations thereof ...." *Id.* at page 35, ll. 8-12. And the Office expressly recognizes that "animal models are reasonably representations of safety and efficacy in humans." Office Action at page 5. Thus, the Office's assertion of

a lack of enablement is unfounded and fails to satisfy the initial burden of showing a lack of enablement.

The Office's references to different treatment methods described by Zorrilla et al. and Zigman et al., which are particularly directed to vaccines and other medical treatments, are inapposite to the present claims.

Applicants submit that the present specification sufficiently enables the skilled artisan to make and use the invention disclosed. Accordingly, withdrawal of the § 112, first paragraph, rejection is requested.

IV. Rejection Under 35 U.S.C. § 102

Claims 13-22, 37-39, 42-45, 49, and 50 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent No. 5,502,077 to Breivik et al. ("Breivik"). Office Action at page 6. Applicants respectfully traverse the rejection.

To show anticipation under § 102, a prior art reference must teach every element of the claim being rejected. M.P.E.P. § 2131. Breivik teaches fatty acid compositions useful in the treatment of prophylaxis of multiple risk factors for cardiovascular disease. *See* Breivik at abstract.

The Office contends that "Breivik et al. teach the same and exact preferred [EPA:DHA] ratio limitation in the instant claims." Office Action at page 7. Applicants disagree. Breivik teaches a composition having a weight ratio of EPA:DHA of from 1:1 to 2:1, preferably 3:2. *See* Breivik at col. 3, ll. 61-65. Thus, Breivik teaches a preferred composition where EPA ≥ DHA, which is in contrast to the present disclosure. Applicants disclose that "the most preferred effect of the invention concerning weight reduction is accomplished by a fatty acid composition rich in DHA. The term 'rich'

herein includes more or less a fatty acid composition primar[il]y containing DHA (none EPA), or derivatives thereof, and a fatty acid composition where the amount of DHA ≥ EPA." Applicants' specification at page 8, ll. 15-21. Breivik fails to teach (or suggest) a fatty acid composition having DHA ≥ EPA.

Moreover, none of the risk factors listed by Breivik read on Applicants' claims, nor does Breivik even suggest treatment of obesity or an overweight condition, or reduction of body weight. Rather, Breivik's disclosure is directed to hypertension, hypertriglyceridemia, and other "possible medical indications" including artheritis, Crohn's disease, psoriasis, and migraine. *See* Breivik at col. 10, ll. 34-38, and col. 11, ll. 1-7. The disclosure of treatment or prophylaxis of multiple risk factors for cardiovascular diseases does not anticipate, either expressly or inherently, the presently claimed methods for at least one of treatment of obesity, prevention of obesity, treatment of an overweight condition, prevention of an overweight condition, controlling body weight reduction, and prevention of body weight gain.

Accordingly, Breivik fails to teach every element of Applicants' claims, and as such, fails to anticipate the present claims. Applicants therefore request that the Office withdraw this rejection.

V. Rejection Under 35 U.S.C. § 103

Claims 13-22, 41, and 51 are rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Breivik in view of U.S. Patent Application Publication No. 2005/0019372 to Corkey et al. ("Corkey"). Office Action at page 10. Applicants respectfully traverse this rejection.

A rejection under 35 U.S.C. § 103 requires clear articulation of the reason(s) why the claimed invention would have been obvious. *See* M.P.E.P. § 2142, 8th ed., Rev. 6 (September 2007). The Supreme Court further emphasized this in *KSR Int'l Co. v. Teleflex*, stating that support for a § 103 rejection "should be made *explicit*." 127 S.Ct. 1727 (2007) (emphasis added) (citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness")). Here, the Office offers mere conclusory statements that fail to support obviousness of the present claims in view of the references cited.

As Applicants showed above, Breivik teaches a different composition having a weight ratio of EPA:DHA of from 1:1 to 2:1, preferably 3:2, wherein said composition is useful for the treatment of risk factors of cardiovascular disease. *See* Breivik at abstract and at col. 3, ll. 61-65. Again, the Office asserts that "Breivik et al. teach the same and exact preferred ratio limitation in the instant claims." Office Action at page 10. Above, Applicants showed this statement to be untrue. Further, Breivik provides no guidance or suggestion of a fatty acid composition where DHA ≥ EPA, let alone such a composition having therapeutic effects.

The Office then contends that "Breivik further anticipates the claimed invention by teaching that this preferred ratio of EPA:DHA has an advantageous effect on risk factors for cardiovascular diseases." Office Action at page 11. Again, the Office fails to show why the skilled artisan would reasonably expect a treatment for the cardiovascular risk factors discussed by Breivik (e.g., hypertension and hypertriglyceridemia) to have any

benefits regarding body weight. Breivik fails to mention, or even suggest a method of treatment or prevention of an overweight condition, or a method of controlling body weight reduction.

Corkey cannot remedy the numerous deficiencies of Breivik. Corkey discloses dietary products comprising predominantly medium-chain triglycerides (MCT) and/or long-chain triglycerides (LCT), which additionally comprise up to 5% omega-3 fatty acids. *See* Corkey at paragraph [0006]. The Office refers to paragraph [0121] of Corkey, which discusses supplementing medium-chain triglycerides (MCT) with fish oil (FO), comprising the omega-3 fatty acids, in dietary treatment experiments. Office Action at pages 11-12. Corkey only discloses the *combination* of MCT/FO, however, and provides no evidence or discussion of any effects of omega-3 fatty acids alone. Furthermore, Corkey does not provide any information regarding EPA:DHA ratios to rectify the substantial discrepancy between the composition disclosed by Breivik and Applicants' disclosure.

Neither Breivik, nor Corkey, alone or in combination, provide a basis for obviousness over the present claims. Accordingly, Applicants request that the rejection under § 103(a) be withdrawn.

VI. Conclusion

Applicants submit that the rejections are overcome by the foregoing amendments and arguments, and request the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

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